REMARKS

The Office Action dated July 3, 2003 presents the examination of claims 6 and 7. Claims 1-5 are withdrawn from consideration. Claims 1-5 and 7 are canceled. Claim 6 is amended. No new matter is inserted into the application.

Information Disclosure Statement

The Examiner requests submission of a concise explanation of *Jikken Igaku*, 15(9), (1997) in English. Applicants respectfully submit that a concise explanation of *Jikken Igaku*, 15(9), (1997) was provided with the Information Disclosure Statement (IDS) filed on January 5, 2004.

The IDS filed on June 2, 2000 listed the author of *Igaku*, 15(9), (1997) as "Kunio MATSUNAGA et al.", as was printed in the Foreign Search Report. However, upon further review, it became apparent that the Foreign Search Report was in error, as there is no article by "Kunio MATSUNAGA et al."

Instead, Applicants respectfully clarify that Kunio MATSUMOTO et al. is the proper author of *Igaku*, 15(9), (1997). The IDS filed on January 5, 2004 properly listed the author of *Igaku*, 15(9),

(1997) as "Kunio MATSUMOTO et al." Again, a concise explanation of this reference was provided with the IDS of January 5, 2004.

Rejection under 35 U.S.C. § 112, first paragraph

Claim 6

The Examiner maintains the rejection of claim 6 under 35 U.S.C. § 112, first paragraph for allegedly containing subject matter not enabled by the specification. Applicants respectfully traverse. Reconsideration of the claim and withdrawal of the instant rejection are respectfully requested.

On page 4, paragraph 9 of the Office Action, the Examiner argues that the specification enables a method for treating acute renal failure comprising administering an effective amount of HGF by continuous intravenous administration to suppress blood urea nitrogen (BUN) and creatine levels in a patient suffering from acute renal failure, but does not enable a method for treating or preventing renal disease comprising administering an effective amount of HGF by continuous intravenous administration.

In order to gain immediate allowance of the present application, but not to acquiesce to the Examiner's position, claim 6 is amended to substantially recite the subject matter

acknowledged by the Examiner to be enabled. Specifically, claim 6, as amended, is directed to a method for treating renal failure, which comprises administering an effective amount of hepatocyte growth factor (HGF) by continuous intravenous administration to suppress blood urea nitrogen (BUN) and creatine levels in a patient suffering from renal failure.

Nevertheless, it appears from the outstanding Office Action that the Examiner maintains her position that the specification only enables the treatment of "acute" renal failure. Applicants respectfully disagree. As argued in the Reply filed on January 5, 2004, the present invention encompasses a method for treating both acute and chronic renal failure. The Examiner does not address Applicants' arguments in the outstanding Office Action. Therefore, Applicants reiterate herein that the rejection is improper.

Both acute renal failure and chronic renal failure have the same pathologies and are therefore both treatable with HGF. As described in the specification on page 2, lines 4-24, it is well known to a person skilled in the art that HGF is useful for treating both acute and chronic renal failure. Furthermore, the specification describes that acute renal failure is caused by tubulorrhexis (see, page 2, line 8 of the specification). It is

known in the art that chronic renal failure is caused by deterioration of renal tubes (see, EP 0 462 549 A1, included in the IDS of January 5, 2004). Accordingly, both acute and chronic renal failures have substantially the same pathologies. The person skilled in the art can readily understand that the method of the present invention is effective in all types of renal failure, including acute and chronic renal failures.

Finally, Applicants respectfully point out that claim 6 does not recite "preventing" or "renal disease." Thus, the Examiner's arguments that the specification does not enable a method for treating or preventing renal disease are irrelevant. In addition, the Examiner writes extensively on the use of the term "effective amount." However, as noted above, the Examiner states that the specification enables a method for treating acute renal failure comprising administering *an effective amount* of HGF by continuous intravenous administration to suppress blood urea nitrogen (BUN) and creatine levels in a patient suffering from acute renal failure. Therefore, Applicants can only assume that the Examiner does not reject the phrase "effective amount."

Based on the above, Applicants respectfully submit that claim 6 is fully enabled by the specification. Withdrawal of the instant rejection is therefore respectfully requested.

Claim 7

The Examiner also maintains the rejection of claim 7 under 35 U.S.C. § 112, first paragraph for allegedly containing subject matter not enabled by the specification. Claim 7 is canceled, thus rendering the instant rejection moot.

Rejection under 35 U.S.C. § 112, second paragraph

The Examiner rejects 7 under 35 U.S.C. § 112, second paragraph for allegedly being indefinite. Claim 7 is canceled, thus rendering the instant rejection moot.

Conclusion

Applicants respectfully submit that the above remarks and/or amendments fully address and overcome all rejections of record. The present application is now in condition for allowance. The Examiner is respectfully requested to issue a Notice of Allowance indicating that claim 6 is allowed.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Kristi L. Rupert, Ph.D. (Reg. No. 45,702) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

Pursuant to the provisions of 37 C.F.R. §§ 1.17 and 1.136(a), the Applicants hereby petition for an extension of three (3) months to October 19, 2004, in which to file a reply to the Office Action. The required fee of $980.00 is attached to the Notice of Appeal which is being filed concurrently herewith.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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